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The effect of the FIFA 11 prevention programmes on the overall injury rate in football

a systematic review and meta-analysis

Thorborg, K.; Krommes, K.; Esteve, E.; Clausen, M. B.; Bartels, E. M.; Rathleff, Michael Skovdal

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STUDY PROTOCOL:

THE EFFECT OF THE FIFA 11 PREVENTION PROGRAMMES ON THE OVERALL INJURY RATE IN FOOTBALL: A SYSTEMATIC REVIEW AND META-ANALYSIS

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AUTHORS:

Thorborg K (1, 2) Krommes K (1), Esteve E (1, 2, 3), Clausen MB (1,2,4), Bartels EM (5), Rathleff MS (6, 7)

AFFILIATIONS:

(1) Department of Orthopaedic Surgery, Sports Orthopedic Research Center, Amager-Hvidovre Hospital, Faculty of Health Sciences, University of Copenhagen, Denmark

(2) Physical Medicine and Rehabilitation – Copenhagen (PMR-C), Amager-Hvidovre Hospital, Copenhagen University Hospital

(3) Sportclinic, Physiotherapy and Sports Training Center, Girona, Catalonia, Spain

(4) Bachelor's Degree Programme in Physiotherapy, Department of Physiotherapy and Occupational Therapy, Faculty of Health and Technology, Metropolitan University College, Copenhagen, Denmark

(5) The Parker Institute, Copenhagen University Hospital, Bispebjerg and Frederiksberg, Copenhagen, Denmark

(6) Center for Sensory-Motor Interaction, Department of Health Science and Technology, Aalborg University, Fredrik Bajers Vej 7E-1, Aalborg, Denmark

(7) Department of Occupational Therapy and Physiotherapy, Aalborg University Hospital, Soendre Skovvej 15, 9000 Aalborg, Denmark.

CORRESPONDING AUTHOR:

Kristian Thorborg, from Department of Orthopaedic Surgery, Sports Orthopedic Research Center, Amager-Hvidovre Hospital, Faculty of Health Sciences, University of Copenhagen, Denmark

KEYWORDS:

Football, Prevention, FIFA, Sports Injuries, Lower limb injuries

INTRODUCTION

More than 265 million people around the world are estimated by Fédération Internationale de Football Association (FIFA) to participate regularly in football (soccer).[1] Football has been recognised, together with running, as one of the most promising sport and leisure time activities to induce important health benefits.[2] Football improves cardiovascular and metabolic health,[2] and prevent risk factors for lifestyle diseases such as diabetes and hypertension.[3] However, football includes an inherent risk of injury,[4;5] which is why injury prevention in football is crucial.[6] Not only does it keep people playing, it also makes it possible to achieve the health benefits associated with the game. Each year 5.8 million people are treated at the hospital treatment due to injuries associated with sports.[7] Team ball sports account for 43% of all hospital-related sports treatment – and football accounts for the majority (67%) of these.[7] The FIFA Medical Assessment and Research Centre (F-MARC) recently decided to combine the direct health effects of playing the game with education and prevention, and has in connection with this created a comprehensive football-based health education programme called "11 for Health".[3;8]

FIFA has since 2004 been focusing on strategies for injury prevention by introducing the FIFA 11 programme for injury prevention in football.[9] FIFA's medical research centre (F-MARC) developed and tested the FIFA 11 programme which has been applied in different areas of organised football to prevent and reduce injury among the many people participating in the sport at the amateur and grassroots level.[6;9] The programme includes specific strengthening, balancing and plyometric exercises, and is to be included during a structured warm-up session. It has been tested in different football cohorts with varying results.[10] Two variations of the 11 programme have been developed and provided by FIFA, the FIFA 11 and the FIFA 11+.[10] The FIFA 11+ is a revised version of the original FIFA 11 programme.[10-12] The FIFA 11+ includes similar key exercises as the FIFA 11 with minor additions, including a more dynamic warm-up and a more specific progression model for the included exercises, to allow for more variation and physical improvement.[10-12] In this way, it aims for optimising improvements in strength, balance and plyometric ability, which may lead to injury reduction.[10-12]

The reason for revising the 11 programme in 2006 was that the 11 programme was found unsuccessful in reducing injury based upon a single study.[11;12] However, a finding of no differences in injury estimates from a single study cannot be considered proof of no effect. Simply, this could be due to insufficient power to detect reductions in injury rates of less than the 40%, which the first FIFA 11 trial was powered to detect.[12] This means that relevant effects on injury reduction of less than 40% could potentially exist from the FIFA 11 programmes, but that an increased number of participants may be needed to detect such a difference. Pooling data from individual studies into a meta-analysis offer an opportunity to increase statistical power and test whether the FIFA programmes are associated with injury reduction, as originally hypothesized in the initial studies where FIFA was involved.[10-12]

With an increase over recent years in the number of studies investigating the preventive effect of the FIFA 11 programmes,[10] with the first study being initiated in 2004,[9] it now seems timely to address the important question: Is there a preventive (injury reducing) effect of the FIFA 11 programme on the overall injury rate in football players? Now, more than ever, this questions is of particular relevance, as it was recently proclaimed by Bizzini and Dvorak (2015) from the F-MARC group, in a narrative review in British Journal of Sports medicine,[6] that by "prioritising injury prevention through the 11+ programme leading to protecting a football player" overall health will be further pursued by FIFA and F-MARC through worldwide promotion of the FIFA 11+ prevention programme among the member associations. This with the specific strategic goal: "to prevent football injuries and to promote football as a health-enhancing leisure activity, improving social

behaviour".[6] While such a strategy is clearly relevant and appealing, it also relies on the premise that the FIFA 11 programmes are actually capable of reducing the overall number football injuries, which from individual studies does not seem to be a consistent finding in the existing literature.[10]

Thus, the primary objective of the present study is, based on available (published) studies, to investigate the effect, positive as well as negative, of the FIFA 11 prevention programmes compared with control interventions (no or sham interventions), on the overall injury rate in football.

We hypothesize that the FIFA 11 programmes will reduce the overall injury rate compared to control (no or sham intervention) in football.

METHODS

Literature search

We will conduct a systematic review following the PRISMA statement[13] and prospectively register the review in PROSPERO. We will carry out a systematic search in the following bibliographic databases: Medline via Pubmed, Embase via OVID, CINAHL via Ebsco, Web of Science, SportDiscus and Cochrane Central Register of Controlled Trials, from 2004 to 15th of July 2015, as the FIFA 11 prevention programmes were initiated and implemented from 2004-2005.[9;14] A hand-search of the reference lists of relevant articles will also be conducted for other potential relevant references and FIFA - Medical Assessment and Research Centre (F-MARC) will be contacted to verify if any important FIFA 11 or FIFA 11+ studies/publications do not appear from the search. No restrictions on language will be included in the search. The complete search will be updated again later during the systematic review process period, but before the final data analysis, to make sure that the literature search is as updated as possible in relation to submission for publication.

The following search strategy was tested to be the most efficient across databases, and will be applied in all the databases mentioned above:

(fifa OR f-marc OR fmarc OR prevention program* OR warm-up program* OR warm up program* OR the11)

AND

(football OR foot ball OR soccer)

Study selection

For estimating the effect of the FIFA 11 programmes on injury rates we will only include randomised or cluster randomised controlled trials comparing the FIFA 11 prevention programmes with a control (no or sham intervention) among football players. To be included studies have to fulfil the following criteria: (1) Full-text paper published in peer-reviewed journal shall be available; (2) Contain original data from a randomised or a cluster randomised trial; (3) Evaluate the preventive effect of FIFA 11 or the FIFA 11+ programme; (4) Include football players only (5) Investigate football injury as the outcome.

Compliance to the FIFA 11 or the FIFA 11+ programmes will be investigated from the included randomised and/or cluster randomised studies.

In the search of possible adverse events reported in relation to actually performing the FIFA 11 programmes (adverse events experienced while performing the programmes), we will also include

all other original studies or reports including practical execution of the FIFA 11 programmes. This in order to look at possible adverse events related to the FIFA 11 programmes in football players. Possible adverse events will be reported as a secondary outcome in this systematic review.

Possible relevant studies, identified by titles and abstracts, from the search are downloaded into Reference Manager and duplicates are removed. Two authors (KT and KK) will independently perform the selection of studies based on the full references given by the bibliographic databases. This will be followed by full text evaluation of the selected studies from the first selection step. Disagreement between the two reviewers will be solved by consensus involving a third reviewer (EMB).

Data extraction and risk of bias assessment

Two reviewers (EE and MBC) will independently extract data using a specifically designed standardized data extracting form (Appendix 1) and compare the extracted data afterwards for consistency. All inconsistencies between the two forms will be resolved by discussion between the two data extractors. Any disagreement between the data extractors after the initial discussion related to inconsistencies between the two individual data extractions will be solved involving a third person (EMB). General study information, participants and intervention characteristics, compliance, adverse events, withdrawals and outcome measures will be extracted (Appendix 1). If data is not available from tables or the result section, the authors of the study in question will be contacted. Whenever possible, results from the intention-to-treat population will be used.

Included randomised and cluster-randomised studies will be assessed for risk of bias by two independent raters (EE and MBC) using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials.[15] Each trial will be evaluated across seven domains of bias, including one or more items that are appraised in two parts. Firstly, the relevant trials' characteristics related to the item will be summarized. Secondly, each bias domain is judged as high or low risk of bias, according to their possible effect on the results of the trial. When the possible effect is unknown or insufficient detail is reported, the item is judged as unclear. All the above concerning risk of bias will follow the description in the Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 2: 8.5.1).[15] When we assess risk of bias in cluster-randomised trials, particular types of bias are included in the "other bias" domain, according to how to assess risk of bias in cluster-randomised trials recommended in Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 3: 16.3.2).[15] Any disagreements between ratings will be resolved by discussion between the raters. Consultation with a third party (EMB) will be used if disagreements still appear after this discussion. An assessment of the methodological quality will not be performed, as no evidence for such appraisals and judgements exists and therefore can be misleading when interpreting the results.[15] The use of quality scales and summary scores is considered problematic due to considerable variations between items and dimensions covered in these scales, with little evidence relating to the internal validity of these assessments.[16]

The risk of bias assessment includes the following seven domains: Random sequence generation (selection bias), Allocation concealment (selection bias), blinding of participants and researchers (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias (including specific bias for cluster-designed studies). High risk of bias is to be expected from the domains concerning blinding of participants and researchers (performance bias), and blinding of outcome assessment (detection bias). This, because in prevention studies using active exercise programmes, such as the FIFA 11 programme, it is not possible to blind the participants from the intervention, or the outcome assessment as the reporting of injuries are self-reported by definition in such studies.

Therefore, risk of bias assessment was followed as recommended by Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 2: 8.5.1)[15] and (Part 3: 16.3.2)[15] but not considered for sensitivity analyses in the final evaluation of the primary or the secondary outcome (The risk of bias assessment form can be seen in Appendix 2)

Primary outcome

Overall injury incidence defined as the number of injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period in both training and match.

Secondary Outcomes

Overall injury incidence defined as the number of injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period in both training and match.

Lower limb injury incidence defined as the number of lower limb injuries per 1000 hours of football exposure. This includes all lower limb injuries (overuse and traumatic) sustained during the study period in both training and match.

Region specific lower limb injury incidence for hamstring, knee and ankle, respectively, defined as the number of these injuries per 1000 hours of football exposure. This includes all injuries (overuse and traumatic) sustained during the study period for each of these regional injuries in both training and match.

Compliance to the intervention will be estimated as the number of FIFA prevention programme sessions performed during the intervention period divided by the length of the intervention period in months. The mean compliance for each study included in the primary analysis will be estimated from data available in the included trials. For the same trials the compliance for each individual team will be estimated from similar data, at team level, obtained directly from the authors of the original trials. Accordingly, data at team level will be obtained on: Total number of injuries; Total exposure time (hours); Number of FIFA prevention programme sessions performed, and the duration of the FIFA prevention programme exercise period (months). The first author of this systematic review (KT) will contact corresponding authors of all randomised and cluster randomised studies included in the primary analysis concerning these compliance/injury data, and ask them to provide this information in a pre-specified form on compliance and injury rates at team level (Appendix 3).

Reports on the number and type(s) of adverse effects related to the actual execution of the FIFA programmes (experienced while performing the prevention exercises) in relation to the number of players in the studies, will be reported.

Data synthesis and analyses

Primary analysis

The incidence rate ratio (IRR) and 95% confidence intervals will be estimated as relative effect size using the extracted data on the overall injury incidence (typically reported as the total number of injuries per 1000 hours), as this is predefined as the primary outcome. If the injury incidence is not available in the published article the first author (KT) of the systematic review will send an email to the author(s) and ask for the data. If exposure is not available, we will use the number of injuries instead.

If cluster randomised trials provide a cluster-adjusted estimate, we will use it. If trials don't report the cluster-adjusted estimates we will use the intra-cluster correlations coefficient (ICC) from their own trial (if reported) or use the intra-cluster correlations coefficient (ICC) from similar trials to adjust for a potential cluster effect by calculating the inflation factor (IF). The equation for cluster adjustment is IF= 1+(n-1)ρ, where ρ is the intracluster correlation coefficient, n the average cluster size and IF the inflation factor.[15;17] Effective sample size is calculated by dividing the number of injuries and amount of exposure hours with the IF as described in the Cochrane Handbook for Systematic Review of Interventions, version 5.1 (Part 3: 16.3.4).[15]

Review Manager version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration) will be used when calculating the pooled IRR. A forest plot will be used to allow for easy visual comparisons between studies. The level of statistical heterogeneity for pooled data will be established using the χ^2 and I^2 statistics. The χ^2 and I^2 statistics describe heterogeneity or homogeneity of the comparisons with $p<0.05$ indicating a significant heterogeneity.[18] The Mantel-Haenszel[19;20] random effects method will be selected as default option.

Secondary exploratory analyses

IRR and 95% confidence intervals will be estimated as relative effect size using the extracted data on the incidence of all lower limb injuries, and for overall injuries in the following subgroups: gender (male and female), and mean age groups (youth (<19 years), Senior (19-30 years), Old girls/boys (31-39 years), Veteran (>39 years)), and type of programme (FIFA 11 or FIFA 11+). If mean age is not provided, then median age will be used for the same age categories. The association between compliance to the programme and the injury incidence will be performed in two ways: one on study level and one on team level. The association between compliance and preventive effect will be analysed through estimating the association between the injury incidence from the individual studies and the average compliance in the individual studies using meta-regression analysis in Stata. To counteract a potential heterogeneous compliance between the teams in the individual studies, we will also estimate the association between the injury incidence and the compliance at team level using Poisson regression as previous done by Soligard et al (2010).[21] This analysis will only include teams randomised to the prevention intervention (meaning one of the FIFA programmes).

Post-hoc analysis

Any other analysis deviating from the planned analyses will be considered post-hoc analysis.

Implementation of statistical analyses plan

This statistical analyses plan (SAP) will be used as a work description for the person performing the statistical analyses (MSR). All analyses will be performed by the same person (MSR), and none of the other investigators involved in this trial will perform any of the statistical analyses. The implementation of the SAP will be as follows: 1. A "data extraction form" will be outlined in collaboration between the principal investigator (KT) and senior author (MSR). The authors involved in the data extraction (EE) and (MBC) will code each intervention arm into 'group A' and 'group B', and thus leave all others blinded from intervention applied during the analyses. Blinded data will be delivered by EE and MBC to MSR according to the "data extraction form". Primary and secondary analyses concerning the comparison of the two groups (intervention versus no or sham intervention) will be carried out blinded from intervention form. Results will be presented by MSR to the writing committee of the systematic review (identical to all authors of this systematic review). The writing committee will then unblind the analyses and thereby find out which of the pre-planned conclusions that should to be used in the first line of the conclusion in the manuscript (defined below). Any queries or disagreements concerning the conclusion in relation to the

primary hypothesis will be discussed in the writing committee, and any final deviations from this will be specified in the discussion and conclusion section of the final manuscript and research publication. The primary hypothesis and the related pre-planned conclusion possibilities are outlined in the following section.

Primary hypothesis and pre-planned conclusion

As our primary hypothesis is that the FIFA 11 programmes will reduce the overall injury rate compared to control (no or sham intervention) in football, we will test this hypothesis. One of three possible scenarios can be expected.

1) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) are below 1, and does not include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

An injury preventive effect of the FIFA 11 programmes compared to control (no or sham intervention) could be documented in football.

2) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

No injury preventive effect of the FIFA 11 programmes compared to control (no or sham intervention) could be documented in football.

3) If the 95% confidence intervals (95%CI) of the incidence rate ratio (IRR) are above 1, and does not include 1, we will in the first line of the conclusion in both manuscript and abstract conclude that:

In contrast to our hypothesis, that the FIFA 11 programmes compared to control (no or sham intervention) will reduce injuries, the data shows that the FIFA 11 programmes are associated with an increased number of injuries compared to control (no or sham intervention) in football.

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APPENDIX 1:

DATA EXTRACTION FORM

Reviewer:	Date:	Study number:

GENERAL STUDY INFORMATION

First author (e.g. Smith F):

Correspondence to: ◻ Detail not provided

Title:

Journal:

Year of publication: **Vol.:** **Num.:** **Pages:**

Country: **Language:**

Sources of support:

STUDY DESIGN

◻ Randomised Controlled Trial

◻ Cluster Randomised Controlled Trial

◻ Not Randomised Trial (jump to non-randomised section)

Setting: ◻Unicenter ◻Multicenter (◻National / ◻International) ◻ Detail not provided

Recruitment period (months): ◻ Detail not provided

STUDY POPULATION AND PARTICIPANTS

Study population description:

Inclusion criteria:

Exclusion criteria:

Flow of participants		
	Groups Intervention / Control	**Reasons / Details**
Invited to participate		
Declined to participate		
Excluded		
Randomized		
Dropouts		
Completed		
Analysed		

Baseline characteristics				
Variables	**Total: (n=)**	**Intervention (n=)**	**Control (n=)**	**Between group difference (statistically significant)**
Age ( )				☐ Yes ☐ No
Gender (M/F)				☐ Yes ☐ No
Weight ( )				☐ Yes ☐ No
Height ( )				☐ Yes ☐ No
BMI ( )				☐ Yes ☐ No
				☐ Yes ☐ No

INTERVENTION

Intervention general description and objectives:

Duration (weeks/months):

Intervention characteristics				
Group	**Programme**	**Supervision**	**Frequency**	**Session duration**
Intervention	☐ The 11 ☐ The 11+			
Control				

DATA COLLECTION

Follow up (months):

Definition of injury: ☐ Yes ☐No

If yes:

☐Time loss

☐Medical attention

☐Other (describe):

Data collection procedures				
Variables	**Responsible (who collected data)**	**Method (scale, instrument, etc.)**	**Frequency of collection**	**Details**
Exposure time				
Number of injuries				
Characteristic of injuries				
Compliance with the intervention				

RESULTS

Drop-outs		
Group	**Num. (%)**	**Description/Reasons**
Total		
Intervention		
Control		

Exposure (h)			
	Total exposure	**Intervention**	**Control**
Total			
Training			
Match			

Results on injury incidence including 95% confidence interval		
	Intervention (n=)	**Control (n=)**
Overall injury incidence		
Lower limb injury incidence		
Hamstrings injury		
Knee injury incidence		
Ankle injury incidence		

Results on number of injuries			
	Total (n=)	**Intervention (n=)**	**Control (n=)**
Number of overall injuries			
Number of lower limb injuries			
Number of hamstrings injuries			
Number of knee injuries			
Number of ankle injuries			

Compliance	
Pre-defined compliance in the study: □ **Yes** □ **No** **If yes, describe:**	
Main descriptions of interest	**Intervention Group**
Number of times that the prevention programme was performed during the intervention period	
Proportion of preventive intervention sessions performed in relation to preventive intervention sessions initially planned (%)	
Proportion of training/match sessions in which the preventive programme was performed in relation to the total number of training/match sessions during the intervention (%)	

ADVERSE EVENTS

Adverse events reported in relation to performing (during) the prevention programme		
Registering adverse events	☐ Yes ☐ No	
Results	**Total:**	**Intervention group:**
Descriptions (type of adverse events, etc.):		

CONCLUSIONS

Conclusions
Primary outcome:

COMMENTS
(Add general comments if relevant)

METHODOLOGICAL DETAILS

Methodological details		
		Description / details
Eligibility criteria specified	☐ Yes ☐ No	
Power calculation	☐ Yes ☐ No ☐ Not reported	
Estimated ICC for power calculation	☐ Yes ☐ No (if yes, provide ICC value in description / details)	
Method of randomization	☐ Adequate / computer generated ☐ Inadequate ☐ Not reported	
Allocation concealment	☐ Adequate ☐ Doubtful ☐ Inadequate ☐ Not reported	
Blinding	Participants: ☐ Yes ☐ No Therapist/s: ☐ Yes ☐ No Outcome assessor/s: ☐Yes ☐ No ☐ Not reported	
Follow up	Same duration for all players? ☐ Yes (Duration: months) ☐ No (Mean duration: months) ☐ Not reported	
Handling of withdrawals description	☐ Yes ☐ No ☐ Not reported	
Intent to Treat	☐ Yes ☐ No ☐ Not reported	
Pre-published study protocol	☐ Yes ☐ No	

Additional data to be extracted for Cluster Randomised Controlled Trials		**Description / details**
Taking clustering effects into account during analyses	☐ Yes ☐ No ☐ Not reported	
Reported ICC related to clustering effects	☐ Yes ☐ No (if yes, provide ICC value in description / details)	
Comparable clusters at baseline	☐ Yes ☐ No ☐ Not reported	
Recruitment after randomisation	☐ Yes ☐ No ☐ Not reported	
Number of clusters in control and intervention group	☐ Yes ☐ No ☐ Not reported	Intervention Control
Average cluster size	☐ Yes ☐ No ☐ Not reported	Intervention Control

SECTION ONLY FOR NOT RANDOMISED TRIALS

STUDY POPULATION AND PARTICIPANTS

Study population description:

Baseline characteristics				
Variables	**Total: (n=)**	**Intervention (n=)**	**Control (n=)**	**Between group difference (statistically significant)**
Age ( )				☐ Yes ☐ No
Gender (M/F)				☐ Yes ☐ No
Weight ( )				☐ Yes ☐ No
Height ( )				☐ Yes ☐ No
BMI ( )				☐ Yes ☐ No
				☐ Yes ☐ No

INTERVENTION

Intervention general description and objectives:

Duration (weeks/months):

Intervention characteristics				
Group	**Programme**	**Supervision**	**Frequency**	**Session duration**
Intervention	☐ The 11 ☐ The 11+			
Control				

ADVERSE EVENTS

Adverse events reported in relation to performing (during) the prevention programme		
Registering adverse events	☐ Yes ☐ No	
Results	**Total:**	**Intervention group:**
Others descriptions:		

COMMENTS
(Add general comments of the article if relevant)

APPENDIX 2:

RISK OF BIAS ASSESSMENT FORM

Reviewer:

First author (year): ( ) Assessment data: Study number:		
Bias domain	**Author's judgment (low, unclear, high)**	**Support for judgment**
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and researchers (performance bias)		
Blinding of outcome assessment (detection bias)		
Incomplete outcome data (attrition bias)		
Selective reporting (reporting bias)		
Other bias		

APPENDIX 3:

REQUESTED INFORMATION FORM FROM CORRESPONDING AUTHORS OF ALL INCLUDED RANDOMISED OR CLUSTER RANDOMISED TRIALS (COMPLIANCE AND INJURY RATES AT TEAM LEVEL)

Team_ID	Total number of injuries (overall)	Total exposure time (hours)	Number of FIFA 11/11+ sessions performed	Duration of the FIFA 11/11+ exercise period (months)